

*egc***IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Patentees : Joseph Grayzel and Jeffrey Grayzel  
Patent No. : 6,942,680 *B2*  
Issued : September 13, 2005  
Application No.: : 09/912,008  
Filed : July 24, 2001  
For : **STIFFENED BALLOON CATHETER FOR  
DILATATION AND STENTING**



**Certificate**  
**APR 11 2006**  
**of Correction**

Certificate of Correction Branch  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

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**TRANSMITTAL LETTER**

Sir:

Transmitted herewith is:

- [X] Request For A Certificate Of Correction Under 37 C.F.R. § 1.322 with an attached Exhibit A  
[X] Certificate of Correction (Form PTO/SB/44)  
[X] No fees are believed necessary for entry of this request. However, if any fees are due for the Request For A Certificate Of Correction Under 37 C.F.R. § 1.322, please charge any such fees to Deposit Account No. 50-0540.  
[X] Acknowledgement postcard.  
[X] Address all future communications to: **CUSTOMER NO. 31013**.

Dated: April 4, 2006

Respectfully submitted,

By:

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**APR 12 2006**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Patentees : Joseph Grayzel and Jeffrey Grayzel  
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A handwritten signature in black ink, appearing to read "Theodore J. Grayzel", written over a horizontal line.

**REQUEST FOR A CERTIFICATE OF CORRECTION  
UNDER 37 C.F.R. § 1.322**

Sir:

Patentees respectfully request that the Patent and Trademark Office issue a Certificate of Correction for the above-identified U.S. Patent No. 6,942,680. Enclosed is one sheet of Form PTO/SB/44 listing one (1) error in the issued patent.

This error is clerical in nature and is believed to be the responsibility of the PTO. The proposed correction does not involve changes which would constitute new matter or require reexamination. The error appears in Claim 143. The correct language appears in the Amendment submitted by the Applicants on January 26, 2005 and attached as Exhibit A.

**APR 12 2006**

Patentees request correction as follows:

Column 18, line 8, Claim 143 insert --flexible than-- between "less" and "said."

(See Exhibit A, p. 20-21, Claim 167).

No fee is believed due for this Certificate of Correction since the errors are believed to be the responsibility of the PTO. However, if any fee is due, the Commissioner is hereby authorized to charge any such fee in connection with this request to Deposit Account No. 50-0540.

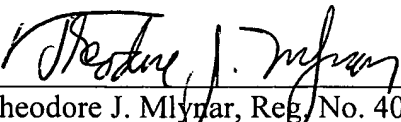
Please direct all correspondence regarding this Request For A Certificate Of Correction to **Customer No. 31013**.

Should there be any questions about the present request for a Certificate of Correction, the Patent Office is invited to contact the undersigned by telephone.

Dated: April 4, 2006

Respectfully submitted,

By: \_\_\_\_\_

  
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# EXHIBIT A

APR 12 2006

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Grayzel et al.

Serial No.: 09/912,008

Filed: July 24, 2001

Group Art Unit: 3731

Examiner: V. Bui

For: STIFFENED BALLOON CATHETER FOR DILATATION  
AND STENTINGMAIL STOP AMENDMENT  
Commissioner For Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

## CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: MAIL STOP AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on January 26, 2005

Signature: 

Clinton Stauffer

AMENDMENT

Sir:

This Amendment is submitted in response to the Notice of Non-Compliant Amendment (37 C.F.R. § 1.121) mailed on November 30, 2004, concerning Applicant's Amendment filed on November 15, 2004, in response to the Office Action mailed on July 15, 2004. Applicant has set forth the complete text for all pending claims, including withdrawn claims 24-32 and 41-47. Otherwise, this Amendment contains all of the content of the Amendment filed on November 15, 2004.

Applicants have enclosed herewith a Request for a one (1) month extension of time to reply to the Notice of Non-Compliant Amendment. Accordingly, this Amendment is being timely submitted.

**Claim amendments begin on page 2.**

**Remarks begin on page 23.**

In response to the Office Action mailed July 15, 2004, please consider and enter into the record the following amendments and remarks:

**IN THE CLAIMS:**

1. (currently amended) A stiffened dilating balloon for use in the human body comprising:

an expandable balloon including a plurality of longitudinally discontinuous stiffening members disposed along a perimeter of said balloon;

wherein said balloon is made of a flexible material;

wherein the stiffening members are less flexible than said balloon;

wherein at least one of the stiffening members is directly connected to another one of the stiffening members by a filament; and

wherein each stiffening member affects a configuration of an area of said perimeter.

2. (previously amended) The balloon of claim 1 wherein the connected stiffening members are longitudinally aligned.

3. (previously amended) The balloon of claim 1 wherein the connected stiffening members are arranged at said perimeter in a staggered configuration.

4. (previously amended) The balloon of claim 3 wherein the connected stiffening members are arranged in a grid pattern.

5. (previously amended) The balloon of claim 1 wherein at least one of the connected stiffening members overlaps another one of the connected stiffening members.

6. (previously amended) The balloon of claim 1 wherein at least one of the connected stiffening members interdigitates with another one of the connected stiffening members.

7. (previously amended) The balloon of claim 1 wherein said filament is elastic.

8. (previously amended) The balloon of claim 1 wherein the connected stiffening members have a geometric shape.

9. (previously amended) The balloon of claim 1 wherein the connected stiffening members have a cross-section with a perimeter that includes a curvilinear portion.

10. (previously amended) The balloon of claim 1 wherein the connected stiffening members have a polygonal cross-section.

11. (previously amended) The balloon of claim 1 wherein the connected stiffening members include at least one raised surface.

12. (previously amended) The balloon of claim 11 wherein a raised surface is substantially smooth.

13. (previously amended) The balloon of claim 11 wherein a raised surface is substantially pointed.

14. (previously amended) The balloon of claim 11 wherein a raised surface is sufficiently sharp to pierce an occlusive material.

15. (previously amended) The balloon of claim 11 wherein a raised surface comprises a saw-tooth cutting element.

16. (previously amended) The balloon of claim 1 wherein the connected stiffening members are disposed along the perimeter of only a longitudinally central region of said balloon.

17. (previously amended) The balloon of claim 1 wherein at least one of the connected stiffening members comprises means for engaging an occlusive material in a lumen.

18. (previously amended) The balloon of claim 1 wherein at least one of the connected stiffening members comprises means for piercing an occlusive material in a lumen.

19. (previously amended) The balloon of claim 1 wherein at least one of the connected stiffening members comprises means for removably coupling to a stent.

20. (previously amended) The balloon of claim 1 wherein at least one of the connected stiffening members comprises means for removably coupling to a stent-graft.

21. (previously amended) The balloon of claim 1 wherein at least one of the connected stiffening members is located within said balloon abutting an inner surface of said balloon.

22. (previously amended) The balloon of claim 1 wherein a portion of at least one of the connected stiffening members is radio-opaque.

23. (previously amended) The balloon of claim 1 wherein the connected stiffening members are disposed on a sheet of material adapted to be applied to said balloon.

24. (withdrawn) A stiffened balloon comprising:  
an expandable balloon including a plurality of longitudinally continuous stiffening members disposed along a perimeter of said balloon;  
wherein said balloon is made of a flexible material;  
wherein the stiffening members are less flexible than said balloon;  
wherein each stiffening member affects a configuration of an area of said perimeter; and



wherein at least one of the stiffening members includes a projection adapted to temporarily retain a device at said balloon.

25. (withdrawn) The balloon of claim 24 wherein said device is a stent.

26. (withdrawn) The balloon of claim 24 wherein said device is a stent-graft.

27. (withdrawn) The balloon of claim 24 wherein at least one of the stiffening members is adapted to interdigitate with a device to temporarily retain said device at said balloon.

28. (withdrawn) The balloon of claim 27 wherein said device is a stent.

29. (withdrawn) The balloon of claim 28 wherein said stent includes at least one of an opening and an interface complementary to at least one of the projections.

30. (withdrawn) The balloon of claim 27 wherein said device is a stent-graft.

31. (withdrawn) The balloon of claim 30 wherein said stent-graft includes at least one of an opening and an interface complementary to at least one of the projections.

32. (withdrawn) The balloon of claim 24 wherein at least one of the stiffening members is radio-opaque.

33. (canceled)

34. (canceled)

35. (canceled)

36. (canceled)

37. (canceled)

38. (canceled)

39. (canceled)

40. (canceled)

41. (withdrawn) A method of using a stiffened balloon to dilate a lumen and deploy an expandable device comprising the steps of:

introducing into a lumen a stiffened balloon bearing an expandable device;  
expanding said balloon and said device to cause at least one projection on a stiffener of said balloon to protrude above an outer surface of said stent and engage an inner surface of the lumen;

dilating the lumen; and

deploying said device in the lumen.

42. (withdrawn) The method of claim 41 further comprising the step of piercing an occlusion in the lumen with a projection.

43. (withdrawn) The method of claim 41 wherein the lumen is an artery.

44. (withdrawn) A method of using a stiffened balloon to dilate a lumen and deploy an expandable device comprising the steps of:

interdigitating at least one projection on a stiffener of a stiffened balloon with an expandable device;

introducing into a lumen said stiffened balloon bearing said device;

expanding said balloon and said device;

dilating the lumen; and

deploying said device in the lumen.

45. (withdrawn) A stiffened balloon comprising:  
an expandable balloon including a plurality of longitudinally continuous stiffening members disposed along a perimeter of said balloon;

wherein said balloon is made of a flexible material;

wherein the stiffening members are less flexible than said balloon;

wherein each stiffening member affects a configuration of an area of said perimeter; and

wherein at least one of the stiffening members includes a pivot point where the stiffening member may be bent to facilitate navigation of the balloon through a passage.

46. (withdrawn) A method of reconfiguring a portion of an expandable device deployed at a lumen comprising the steps of:

introducing into the lumen a stiffened balloon bearing a longitudinal stiffener at a first location on the balloon;

aligning said longitudinal stiffener with the portion of the expandable device; and

expanding said balloon to cause said stiffener to exert a first radial force against the portion of the expandable device to reconfigure the portion;

wherein said first radial force is greater than a radial force applied by said balloon at any other location on the balloon.

47. (withdrawn) The method of claim 46 wherein said step of aligning comprises the steps of:

determining an orientation of said longitudinal stiffener with reference to a radio-opaque portion of the stiffener; and

modifying the orientation of said longitudinal stiffener to align with the portion of the expandable device.

48. (previously presented) The balloon of claim 1 wherein said filament is inelastic.

49. (previously presented) The balloon of claim 1 wherein said filament is radio-opaque.

50. (previously presented) The balloon of claim 1 wherein said filament is straight.

51. (previously presented) The balloon of claim 1 wherein said filament is nonlinear.

52. (previously presented) The balloon of claim 1 wherein said at least one stiffening member is connected to a plurality of the stiffening members by a corresponding plurality of filaments.

53. (previously presented) The balloon of claim 1 wherein the connected stiffening members are disposed along the perimeter of only an end region of said balloon.

54. (previously presented) The balloon of claim 1 wherein the connected stiffening members are disposed along the perimeter of a region of said balloon extending longitudinally no more than three-quarters of a length of said balloon.

55. (previously presented) The balloon of claim 1 wherein at least one of the connected stiffening members includes a projection.

56. (previously presented) The balloon of claim 55 wherein said projection is radio-opaque.

57. (previously presented) The balloon of claim 55 wherein said projection has a pointed end.

58. (previously presented) The balloon of claim 55 wherein said projection has a blunt end.

59. (previously presented) The balloon of claim 55 wherein said projection has an end that is sufficiently sharp to pierce an occlusive material.

60. (previously presented) The balloon of claim 55 wherein said projection has an end that is sufficiently sharp to penetrate a vessel wall.

61. (previously presented) The balloon of claim 55 wherein said projection comprises a saw tooth cutting element.

62. (previously presented) The balloon of claim 55 wherein said projection is adapted to removably couple to a device at said balloon.

63. (previously presented) The balloon of claim 62 wherein said device is a stent.

64. (previously presented) The balloon of claim 62 wherein said device is a stent-graft.

65. (previously presented) The balloon of claim 62 wherein said projection is adapted to interdigitate with said device.

66. (previously presented) The balloon of claim 55 wherein said projection is adapted to engage an occlusive material in a lumen.

67. (previously presented) The balloon of claim 55 wherein said projection is adapted to deform an occlusive material in a lumen.

68. (previously presented) The balloon of claim 1 wherein at least one of the connected stiffening members comprises means for removably coupling to a device.

69. (previously presented) The balloon of claim 1 wherein a plurality of the connected stiffening members each includes a projection.

70. (previously presented) The balloon of claim 69 wherein a projection is connected to another projection by a filament.

71. (previously presented) The balloon of claim 69 wherein a projection is connected to a plurality of projections by a corresponding plurality of filaments.

72. (previously presented) The balloon of claim 69 further comprising means for connecting a projection to another projection.

73. (previously presented) The balloon of claim 1 wherein at least one of the connected stiffening members has a geometric shape.

74. (previously presented) The balloon of claim 1 wherein at least one of the connected stiffening members has a cross-section with a perimeter that includes a curvilinear portion.

75. (previously presented) The balloon of claim 1 wherein at least a portion of one of the connected stiffening members has a polygonal cross-section.

76. (previously presented) The balloon of claim 1 wherein at least a portion of one of the connected stiffening members has a rectangular cross-section.

77. (previously presented) The balloon of claim 1 wherein at least a portion of one of the connected stiffening members has a triangular cross-section.

78. (previously presented) The balloon of claim 1 wherein at least one of the connected stiffening members is cylindrical.

79. (previously presented) The balloon of claim 1 wherein at least one of the connected stiffening members is longitudinally straight-walled and has a rectangular cross-section.

80. (previously presented) The balloon of claim 1 wherein the connected stiffening members are disposed along the perimeter of only a limited longitudinal region of said balloon.

81. (previously presented) The balloon of claim 80 wherein said limited longitudinal region has a length no greater than three-quarters of a length of a cylindrical section of said balloon.

82. (previously presented) The balloon of claim 1 wherein at least one of the connected stiffening members is located partly or entirely on an outer surface of a wall of said balloon.

83. (previously presented) The balloon of claim 1 wherein at least one of the connected stiffening members is located entirely within a wall of said balloon.

84. (previously presented) The balloon of claim 1 wherein at least one of the connected stiffening members is located partly or entirely on an inner surface of said balloon.

85. (previously presented) The balloon of claim 1 wherein at least one of the connected stiffening members extends into a wall of said balloon and protrudes from a surface of said balloon.

86. (previously presented) The balloon of claim 5 wherein a portion of a first connected stiffening member extends above an outer surface of said balloon and extends over a portion of a second connected stiffening member.

87. (previously presented) The balloon of claim 86 wherein said first connected stiffening member is in contact with said second connected stiffening member.

88. (previously presented) The balloon of claim 86 wherein said first connected stiffening member is not in contact with said second connected stiffening member.

89. (previously presented) The balloon of claim 86 wherein said first connected stiffening member is connected to said second connected stiffening member by said filament.

90. (previously presented) The balloon of claim 86 wherein said first connected stiffening member is not connected to said second connected stiffening member.

91. (previously presented) The balloon of claim 11 wherein a raised surface is sufficiently sharp to penetrate a vessel wall.

92. (previously presented) The balloon of claim 17 wherein said means for engaging comprises means for deforming said occlusive material.

93. (previously presented) The balloon of claim 17 wherein said means for engaging comprises a projection.

94. (previously presented) The balloon of claim 17 wherein said means for engaging comprises a raised surface.

95. (currently amended) A stiffened dilating balloon catheter comprising:  
an expandable balloon including a plurality of longitudinally discontinuous stiffening members disposed along a perimeter of said balloon;

wherein said balloon is made of a flexible material;

wherein the stiffening members are less flexible than said balloon;

wherein at least one of the stiffening members is directly connected to another one of the stiffening members by a filament; and

wherein each stiffening member affects a configuration of an area of said perimeter.

96. (previously presented) The balloon catheter of claim 95 wherein the connected stiffening members are longitudinally aligned.



97. (previously presented) The balloon catheter of claim 95 wherein the connected stiffening members are arranged at said perimeter in a staggered configuration.

98. (previously presented) The balloon catheter of claim 97 wherein the connected stiffening members are arranged in a grid pattern.

99. (previously presented) The balloon catheter of claim 95 wherein at least one of the connected stiffening members overlaps another one of the connected stiffening members.

100. (previously presented) The balloon catheter of claim 95 wherein at least one of the connected stiffening members interdigitates with another one of the connected stiffening members.

101. (previously presented) The balloon catheter of claim 95 wherein said filament is elastic.

102. (previously presented) The balloon catheter of claim 95 wherein the connected stiffening members have a geometric shape.

103. (previously presented) The balloon catheter of claim 95 wherein the connected stiffening members have a cross-section with a perimeter that includes a curvilinear portion.

104. (previously presented) The balloon catheter of claim 95 wherein the connected stiffening members have a polygonal cross-section.

105. (previously presented) The balloon catheter of claim 95 wherein the connected stiffening members include at least one raised surface.

106. (previously presented) The balloon catheter of claim 105 wherein a raised surface is substantially smooth.

107. (previously presented) The balloon catheter of claim 105 wherein a raised surface is substantially pointed.

108. (previously presented) The balloon catheter of claim 105 wherein a raised surface is sufficiently sharp to pierce an occlusive material.

109. (previously presented) The balloon catheter of claim 105 wherein a raised surface comprises a saw-tooth cutting element.

110. (previously presented) The balloon catheter of claim 95 wherein the connected stiffening members are disposed along the perimeter of only a longitudinally central region of said balloon.

111. (previously presented) The balloon catheter of claim 95 wherein at least one of the connected stiffening members comprises means for engaging an occlusive material in a lumen.

112. (previously presented) The balloon catheter of claim 95 wherein at least one of the connected stiffening members comprises means for piercing an occlusive material in a lumen.

113. (previously presented) The balloon catheter of claim 95 wherein at least one of the connected stiffening members comprises means for removably coupling to a stent.

114. (previously presented) The balloon catheter of claim 95 wherein at least one of the connected stiffening members comprises means for removably coupling to a stent-graft.

115. (previously presented) The balloon catheter of claim 95 wherein at least one of the connected stiffening members is located within said balloon abutting an inner surface of said balloon.

116. (previously presented) The balloon catheter of claim 95 wherein a portion of at least one of the connected stiffening members is radio-opaque.

117. (previously presented) The balloon catheter of claim 95 wherein the connected stiffening members are disposed on a sheet of material adapted to be applied to said balloon.

118. (previously presented) The balloon catheter of claim 95 wherein said filament is inelastic.

119. (previously presented) The balloon catheter of claim 95 wherein said filament is radio-opaque.

120. (previously presented) The balloon catheter of claim 95 wherein said filament is straight.

121. (previously presented) The balloon catheter of claim 95 wherein said filament is nonlinear.

122. (previously presented) The balloon catheter of claim 95 wherein said at least one stiffening member is connected to a plurality of the stiffening members by a corresponding plurality of filaments.

123. (previously presented) The balloon catheter of claim 95 wherein the connected stiffening members are disposed along the perimeter of only an end region of said balloon.

124. (previously presented) The balloon catheter of claim 95 wherein the connected stiffening members are disposed along the perimeter of a region of said balloon extending longitudinally no more than three-quarters of a length of said balloon.

125. (previously presented) The balloon catheter of claim 95 wherein at least one of the connected stiffening members includes a projection.

126. (previously presented) The balloon catheter of claim 125 wherein said projection is radio-opaque.

127. (previously presented) The balloon catheter of claim 125 wherein said projection has a pointed end.

128. (previously presented) The balloon catheter of claim 125 wherein said projection has a blunt end.

129. (previously presented) The balloon catheter of claim 125 wherein said projection has an end that is sufficiently sharp to pierce an occlusive material.

130. (previously presented) The balloon catheter of claim 125 wherein said projection has an end that is sufficiently sharp to penetrate a vessel wall.

131. (previously presented) The balloon catheter of claim 125 wherein said projection comprises a saw tooth cutting element.

132. (previously presented) The balloon catheter of claim 125 wherein said projection is adapted to removably couple to a device at said balloon.

133. (previously presented) The balloon catheter of claim 132 wherein said device is a stent.

134. (previously presented) The balloon catheter of claim 132 wherein said device is a stent-graft.

135. (previously presented) The balloon catheter of claim 132 wherein said projection is adapted to interdigitate with said device.

136. (previously presented) The balloon catheter of claim 125 wherein said projection is adapted to engage an occlusive material in a lumen.

137. (previously presented) The balloon catheter of claim 125 wherein said projection is adapted to deform an occlusive material in a lumen.

138. (previously presented) The balloon catheter of claim 95 wherein at least one of the connected stiffening members comprises means for removably coupling to a device.

139. (previously presented) The balloon catheter of claim 95 wherein a plurality of the connected stiffening members each includes a projection.

140. (previously presented) The balloon catheter of claim 139 wherein a projection is connected to another projection by a filament.

141. (previously presented) The balloon catheter of claim 139 wherein a projection is connected to a plurality of projections by a corresponding plurality of filaments.

142. (previously presented) The balloon catheter of claim 139 further comprising means for connecting a projection to another projection.

143. (previously presented) The balloon catheter of claim 95 wherein at least one of the connected stiffening members has a geometric shape.

144. (previously presented) The balloon catheter of claim 95 wherein at least one of the connected stiffening members has a cross-section with a perimeter that includes a curvilinear portion.

145. (previously presented) The balloon catheter of claim 95 wherein at least a portion of one of the connected stiffening members has a polygonal cross-section.

146. (previously presented) The balloon catheter of claim 95 wherein at least a portion of one of the connected stiffening members has a rectangular cross-section.

147. (previously presented) The balloon catheter of claim 95 wherein at least a portion of one of the connected stiffening members has a triangular cross-section.

148. (previously presented) The balloon catheter of claim 95 wherein at least one of the connected stiffening members is cylindrical.

149. (previously presented) The balloon catheter of claim 95 wherein at least one of the connected stiffening members is longitudinally straight-walled and has a rectangular cross-section.

150. (previously presented) The balloon catheter of claim 95 wherein the connected stiffening members are disposed along the perimeter of only a limited longitudinal region of said balloon.

151. (previously presented) The balloon catheter of claim 150 wherein said limited longitudinal region has a length no greater than three-quarters of a length of a cylindrical section of said balloon.

152. (previously presented) The balloon catheter of claim 95 wherein at least one of the connected stiffening members is located partly or entirely on an outer surface of a wall of said balloon.

153. (previously presented) The balloon catheter of claim 95 wherein at least one of the connected stiffening members is located entirely within a wall of said balloon.

154. (previously presented) The balloon catheter of claim 95 wherein at least one of the connected stiffening members is located partly or entirely on an inner surface of said balloon.

155. (previously presented) The balloon catheter of claim 95 wherein at least one of the connected stiffening members extends into a wall of said balloon and protrudes from a surface of said balloon.

156. (previously presented) The balloon catheter of claim 99 wherein a portion of a first connected stiffening member extends above an outer surface of said balloon and extends over a portion of a second connected stiffening member.

157. (previously presented) The balloon catheter of claim 156 wherein said first connected stiffening member is in contact with said second connected stiffening member.

158. (previously presented) The balloon catheter of claim 156 wherein said first connected stiffening member is not in contact with said second connected stiffening member.

159. (previously presented) The balloon catheter of claim 156 wherein said first connected stiffening member is connected to said second connected stiffening member by said filament.

160. (previously presented) The balloon catheter of claim 156 wherein said first connected stiffening member is not connected to said second connected stiffening member.

161. (previously presented) The balloon catheter of claim 105 wherein a raised surface is sufficiently sharp to penetrate a vessel wall.

162. (previously presented) The balloon catheter of claim 111 wherein said means for engaging comprises means for deforming said occlusive material.

163. (previously presented) The balloon catheter of claim 111 wherein said means for engaging comprises a projection.

164. (previously presented) The balloon catheter of claim 111 wherein said means for engaging comprises a raised surface.

165. (currently amended) A stiffened dilating balloon for use in the human body comprising:

an expandable balloon including a plurality of longitudinally discontinuous stiffening members disposed along a perimeter of said balloon; and

means for directly connecting at least one of the stiffening members to another one of the stiffening members;

wherein said balloon is made of a flexible material;

wherein the stiffening members are less flexible than said balloon; and

wherein each stiffening member affects a configuration of an area of said perimeter.

166. (currently amended) A stiffened dilating balloon catheter comprising:

an expandable balloon including a plurality of longitudinally discontinuous stiffening members disposed along a perimeter of said balloon; and

means for directly connecting at least one of the stiffening members to another one of the stiffening members;

wherein said balloon is made of a flexible material;

wherein the stiffening members are less flexible than said balloon; and

wherein each stiffening member affects a configuration of an area of said perimeter.

167. (previously presented) A method of dilating a portion of a lumen in a human body comprising the steps of:

introducing into said human body an expandable balloon including a plurality of longitudinally discontinuous stiffening members disposed along a perimeter of said balloon;



wherein said balloon is made of a flexible material;

wherein the stiffening members are less flexible than said balloon;

wherein at least one of the stiffening members is connected to another one of the stiffening members by a filament; and

wherein each stiffening member affects a configuration of an area of said perimeter;

positioning said expandable balloon at said portion; and

expanding said expandable balloon to cause the connected stiffening members to exert a first radial force against said portion;

wherein said filament prevents a distance between the connected stiffening members from exceeding a maximum distance; and

wherein said first radial force is greater than a radial force directly applied by an outer surface of said balloon against said portion.

168. (previously presented) The method of claim 167 wherein the step of positioning said expandable balloon includes the step of traversing a tortuous pathway in said human body.

169. (previously presented) The method of claim 167 wherein said portion comprises a stenosis.

170. (previously presented) A method of dilating a device in a lumen in a human body comprising the steps of:

introducing into said human body an expandable balloon including a plurality of longitudinally discontinuous stiffening members disposed along a perimeter of said balloon;

wherein said balloon is made of a flexible material;

wherein the stiffening members are less flexible than said balloon;

wherein at least one of the stiffening members is connected to another one of the stiffening members by a filament; and

wherein each stiffening member affects a configuration of an area of said perimeter;

positioning said expandable balloon at said device; and

expanding said expandable balloon to cause the connected stiffening members to exert a first radial force against said device;

wherein said filament prevents a distance between the connected stiffening members from exceeding a maximum distance; and

wherein said first radial force is greater than a radial force directly applied by an outer surface of said balloon against said device.

171. (previously presented) The method of claim 170 wherein the step of positioning said expandable balloon includes the step of traversing a tortuous pathway in said human body.

172. (previously presented) The method of claim 170 wherein said device is a stent.

173. (previously presented) The method of claim 170 wherein said device is a stent-graft.

**REMARKS**

Claims 1-173 are pending in this application. Claims 24-32 and 41-47 have been withdrawn from consideration. Claims 33-40 have been cancelled.

Claims 1-15, 17-20, 48, 50-52, 55, 57-75, 77, 82, 85-86, 88-109, 111-114, 118, 120-122, 125, 127-145, 147, 152, 156, and 158-171 have been rejected under 35 U.S.C. §102(b) as being anticipated by Schubert (German Patent No. DE 3402573 A1). Applicants respectfully traverse these rejections.

Applicants note that Schubert does not disclose a stiffened dilating balloon comprising a plurality of stiffening members. The “numerous fine individual blades” (1) disclosed by Schubert do not constitute stiffening members in that they are so small, relative to the size of the balloon - see Schubert Figure 8 - that they do not appreciably stiffen the balloon.

Claims 1, 95, 165 and 166 have been amended to clarify the interconnection of the stiffening members. In each claim the word “directly” has been inserted to make clear that at least one of the stiffening members is directly connected to another one of the stiffening members by a filament. In contrast, the Examiner has asserted that “filaments 4 *indirectly* connect[]” blades (1) of Schubert together. While Applicants do not agree with the Examiner’s assertion, Applicants’ amendment of the claims clarifies this difference between the present invention and the disclosure of Schubert.

Applicants disagree with the Examiner’s further assertion that the threads (4) of Schubert “can be considered as elastic or inelastic because “elastic” and “inelastic” are relative terms.” The use of relative terms in claim drafting is a common practice and the meaning of such terms should not be disregarded by the Examiner. There is no suggestion in Schubert that threads (4) are elastic.

Applicants further disagree with the Examiner's assertion that the Schubert reference "inherently discloses a method of using the device as recited in the claims." Applicants request that the Examiner specifically identify the text of Schubert upon which the Examiner relies. "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." M.P.E.P. § 2112 citing *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in the original). Here, the Examiner has not identified any basis at all for a finding of inherency. Applicants maintain that Schubert does not disclose the methods set forth in claims 167-171. Schubert certainly does not disclose the methods of claims 170-171 as Schubert makes no mention at all of using an expandable balloon to dilate a separate device.

Claims 16, 21-23, 49, 53-54, 56, 76, 78, 80-81, 83-84, 87, 110, 115-117, 119, 123-124, 126, 146, 148-151, 153-155, 157 and 172-173 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Schubert. Applicants respectfully traverse these rejections. The Examiner has failed to establish a prima facie case of obviousness. Even if Schubert did "disclose[] substantially all structural limitations of the device as claimed," which it does not, "the mere fact that one of ordinary skill in the art could rearrange parts of the reference device to meet the terms of the claims is not by itself sufficient to support a finding of obviousness. The prior art must find a motivation or reason for the worker in the art, without the benefit of applicants' specification to make the necessary changes in the reference device." M.P.E.P. §2144.04 quoting *Ex Parte Chicago Rawhide Mfg. Co.*, 223 USPQ 351, 353 (Bd. of Pat. App. & Inter. 1984). The Examiner neither identifies any corresponding structure in Schubert nor any

motivation in the prior art to modify that structure and, therefore, has failed to establish any grounds for an obviousness rejection.

Applicants further disagree with the Examiner's assertion in connection with claims 172 and 173 that Schubert discloses "projections to engage and secure a stent/stent-graft during deployment along a tortuous vessel." Claims 172 and 173 do not recite the engagement or securement of a device to a balloon so that the device can be carried through tortuous vessel. These claims are, instead, directed to a method of dilating a stent or stent-graft.

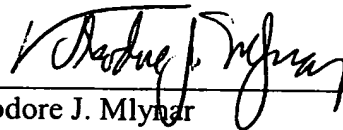
Nevertheless, Schubert makes no suggestion of such a method either. Schubert discloses blade structures for cutting. The inflation of a Schubert device within a stent or stent-graft would likely cause significant damage to the stent or stent-graft since the blades of Schubert would tend to cut the stent or stent-graft. Such mutilation of the stent or stent-graft device would be plainly inconsistent with an effort to deploy such a device.

Applicants note that Claim 79 was not specifically rejected. Clarification is requested.

Early and favorable consideration of the foregoing amendments and remarks are earnestly requested.

Dated: January 26, 2005

Respectfully submitted,



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## UNITED STATES PATENT AND TRADEMARK OFFICE CERTIFICATE OF CORRECTION

Page 1 of 1PATENT NO. : 6,942,680 *B2*

APPLICATION NO.: 09/912,008

ISSUE DATE : September 13, 2005

INVENTOR(S) : Joseph Grayzel and Jeffrey Grayzel

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Claim 143; Column 18:

Line 8, insert --flexible than-- between "less" and "said."

**MAILING ADDRESS OF SENDER (Please do not use customer number below):**

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